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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,262	12/05/2003	Gloria Ro Kolb	FIW-004.01	4713
25181	7590	08/19/2004	EXAMINER	
FOLEY HOAG, LLP PATENT GROUP, WORLD TRADE CENTER WEST 155 SEAPORT BLVD BOSTON, MA 02110			SWEET, THOMAS	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 08/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/731,262	KOLB, GLORIA RO
	<b>Examiner</b>	<b>Art Unit</b>
	Thomas J Sweet	3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 47 and 48 is/are allowed.
- 6) Claim(s) 1-4, 6, 10-18, 20, 22, 25-46 and 49-51 is/are rejected.
- 7) Claim(s) 5, 7-9, 19, 21, 23 and 24 is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | Paper No(s)/Mail Date. ____   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: ____                                     |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell et al (US 6214037) in view of Henner (WO 01/89415). Mitchell et al discloses a stent (fig. 10) comprising a flexible, elongate body having a curled proximal portion (82, fig. 15), a curled distal portion (84, fig. 15), and a main portion extending between the proximal and distal portions (80, fig. 15), wherein; the main and distal portions together define a channel laterally open throughout at least a part of the channel's length (22 or 24). However, Mitchell et al does not disclose the channel being closed along its proximal end. Henner teaches another stent in which the channel is closed along it's proximal end for the purpose of preventing reflux from the bladder (page 11). Mitchell et al also remains silent as to whether the proximal portion is curled away from the channel or not. However, the curled proximal portion is purely an anchoring means, which would work equally well whichever direction it curls, and any variation as such would amount to mere design choice. It would have been obvious to one of ordinary skill in the art at the time the invention was made to close channel of Mitchell et al along it's proximal end as taught by Henner et al for the purpose of preventing reflux from the bladder. Furthermore, It would have been obvious to one of ordinary skill in the art at the time the

invention was made to curl the anchoring portion away from the channel since it would be functionally equivalent and amounts to mere design choice.

Claims 1-4, 10-18, 20, 22, 25-41, 44-46 and 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell et al (US 6214037) in view of Hayner et al (US 6524268). Mitchell et al discloses a stent (fig. 10) comprising a flexible, elongate body having a curled proximal portion (82, fig. 15), a curled distal portion (84, fig. 15), and a main portion extending between the proximal and distal portions (80, fig. 15), wherein; the main and distal portions together define a channel laterally open throughout at least a part of the channel's length (22 or 24). However, Mitchell et al does not disclose the channel not extending along the proximal portion, whereby the channel's proximal end is disposed in the main portion. Hayner et al teaches another stent in which the channel (8) is not extending along the proximal portion (anchoring portion), whereby the channel's proximal end (14) is disposed in the main portion for the purpose of draining at the entrance of the bladder. Mitchell et al also remains silent as to whether the proximal portion is curled away from the channel or not. However, the curled proximal portion is purely an anchoring means, which would work equally well whichever direction it curls, and any variation as such would amount to mere design choice. It would have been obvious to one of ordinary skill in the art at the time the invention was made to end the channel of Mitchell et al at the main portion of the stent, short of the anchoring portion (curled proximal) as taught by Hayner et al for the purpose of draining at the entrance of the bladder. Furthermore, It would have been obvious to one of ordinary skill in the art at the time the invention was made to curl the anchoring portion away from the channel since it would be functionally equivalent and amounts to mere design choice.

With regard to claims 2-4, 18, 20, 25-26 and 31, Mitchell et al discloses that the channel can be discontinuous (col 3, lines 19-25).

With regard to claims 15-17, though exact proportions can not be discerned from figures it appear that at rest in the tube (60) the channel has a gap width within the range of  $\frac{1}{4}$  to  $\frac{1}{3}$  of the channel's diameter. If this is not the case, size variations are within the skill level of one of ordinary skill in the art and are not patentable distinct over the prior art.

With regard to claims 22 and 44-45, tube (60) amounts to a band closing off at least one part of the channel.

With regard to claims 27-29, see figure 1.

With regard to claim 30, see column 1, lines 60-64.

With regard to claim 33 and 50, size variations are within the skill level of one of ordinary skill in the art and are not patentable distinct over the prior art.

With regard to claim 35, see column 3 lines 1-12.

With regard to claims 36-37, see column 5 lines 4-9.

With regard to claims 39-41 and 46, it is common knowledge in the prior art to taper/bevel the ends of a stent (as can be seen in fig. 3, at 22 and fig. 2, at 24 of Hayner et al) for the purpose of enhanced insertion and extraction. It would have been obvious to one of ordinary skill in the art at the time the invention was made to taper/bevel the stent ends of Mitchell et al in order to enhanced insertion and extraction.

With regard to claim 50, Mitchell et al disclose the use of barbs for anchoring (col 3, lines 37-41).

Claims 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell et al in view of Hayner et al as applied to claim 1 above, and further in view of Willard (US 5282784). Mitchell et al as modified discloses a stent as discussed above. However, Mitchell et al remains silent as to whether a hole for a pull string is included. Willard teaches another stent including a hole for a pull string for the purpose of extracting the stent. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a hole for a pull string as taught by Willard on the stent of Mitchell et al in order to attach a pull string for extracting the stent.

With regard to claim 43, the hole placement near the end is a matter of design choice working equally well anywhere near the end and is within the skill level of one of ordinary skill in the art and are not patentable distinct over the prior art.

***Allowable Subject Matter***

Claims 47-48 are allowed.

Claims 5, 7-9, 19, 21 and 23-24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J Sweet whose telephone number is (703) 308-4018. The examiner can normally be reached on 6:30 am - 5:00pm, M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M McDermott can be reached on (703) 308-2111. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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